

REMARKS

Claims 1-47 are pending in the present application, and no claims have been amended in this paper. Claims 1-39 have been withdrawn from consideration by the examiner, and claims 40-47 have been examined.

RESTRICTION OF CLAIMS

The examiner restricted the claims under 35 U.S.C. § 1.21 to Group I, claims 1-5 and 30-39 drawn to a method of applying splints or supports; and Group II, claims 6-29 and 40-47, drawn to a splint or support. Applicant confirms election of the apparatus claims of Group II with traverse.

Applicant traverses on the grounds that the rationale for restriction between the process and apparatus claims is invalid. According to the examiner, in the instant case, the product can be used with a different process. The examiner states that “the splint can be used by activating the hardening material and then applying it to the patient while it is still malleable, or the splint can also be used by applying the splint to the patient and then activating the hardening material.”

In the process claim 1 of Group I, it is acknowledged that “activating said hardenable material” is a step recited before “holding said splint support to the anatomy” of the patient. Similarly, process claim 30 recites “activating said hardenable material” and then “holding said splint support to the anatomy.” However, it is well established in the patent law for interpreting method claims that “[u]nless the steps of a method actually recite an order, the steps are not ordinarily construed to require one.” *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003). It is also improper to import a limitation from the specification into the claims, i.e., the order of steps used by the preferred embodiment. *Id.*

In reference to claims 1 and 30, the steps of “activating said hardenable material” and “holding said splint support to the anatomy” can be taken out of the sequence or order in which these steps were recited in the claims. Therefore, the two ways of using the

splint described by the examiner are covered by method claims 1 and 30. The inventions are therefore not distinct as the examiner contends. Applicant respectfully submits that the apparatus and method claims are directed to a common invention and as such the restriction should be withdrawn.

ELECTION OF SPECIES

The examiner required an election of species from 9 species characterized by the examiner on page 3 of the Office action. Applicant confirms election of species 1, Figure 3, with traverse.

Applicant traverses on the grounds that withdrawn apparatus claims 6-29 also read on the Fig. 3 embodiment in addition to claims 40-47 examined by the examiner. In Fig. 3 of the pending application, a splinting material impregnated with a water activatable material 52 has laterally, outwardly extending “tacking” or “primary” arrangements or strips 54. The splinting material with the tacking or primary arrangements are optionally wrapped by a “secondary” or “functional” arrangement (i.e., tape 30) shown in Fig. 1. As described in paragraph [00054] of the pending application, “in most of the embodiments shown herein, and specifically the embodiments of Figs. 1-7 and 11, the functional securing may be accomplished using flexible elastic tape as indicated in the Fig. 1, or straps as suggested in Fig. 10.”

Therefore, applicant contends that withdrawn independent claims 6 and 25 and their dependent claims read on the Fig. 3 embodiment since the independent claims provide an orthopedic blank impregnated with a hardenable material (52), primary tacking arrangements (54), and secondary holding arrangements (30) for functionally securing the blank in place on the patient (see Fig. 1, and paragraph [00054] of the pending application). Applicant respectfully requests that withdrawn apparatus claims 6-29 be reinstated and examined along with apparatus claims 40-47. Applicant finally contends that claims 6 and 25 are generic and claim 40 is a species thereof wherein the elongate blank is in a roll form.

REJECTION OF CLAIMS

The examiner rejected claims 40-42, 44 and 46 under 35 U.S.C. § 103(a) over U.S. Patent No. 6,106,492 (Darcey) in view of U.S. Patent No. 5,755,678 (Parker et al.). This rejection is respectfully traversed.

According to the examiner, Darcey discloses a splint comprising an elongated blank (14) impregnated with hardenable material, at least one layer of additional non-impregnated material on at least one side of the blank (20), laterally extending primary tacking arrangements (26), and secondary holding arrangements for functionally securing the blank (Fig. 11).

Applicant contends that the straps 26 shown in Figs. 8-10 of Darcey are not “laterally extending primary tacking arrangements” as recited in claim 40 or in withdrawn apparatus claims 6 and 25. Specifically, independent claim 40 provides that the “laterally extending primary tacking arrangements for holding said blank in place on the injured part of the patient’s anatomy in a manner that *still allows adjustment of said blank with respect to the anatomy*” (emphasis added). Withdrawn apparatus claims 6 and 25 provide “primary tacking arrangements for holding said blank in place on the injured part of the patient’s anatomy *in a manner that still allows adjustment of said blank with respect to the anatomy*” (emphasis added).

Paragraph [00013] of the pending application explains that “[t]hese primary securing arrangements may be considered to be temporary ‘tacking’ or locating arrangements, as they permit easy *adjustment of the splint position*; and are usually of *insufficient strength to rigidly immobilize the splint* for long term use by the patient” (emphasis added). The primary tacking arrangements are for temporary use to hold the splint to the limb so that the physician or medical technician has both hands freed to readily position the splint to the precise desired location without the assistance of additional medical personnel. See paragraph [00030] of the pending application.

In contrast, the straps 26 used in the Darcey splint shown in Figs. 9 and 10 are not temporary, are not for “tacking,” and are intended for long-term fixation of the splint (i.e.,

immobilizing the splint) to the injured wrist of the patient. As explained in Darcey (at col. 6, l. 67 - col. 7, ll. 1-4), the two splints 14 as applied in the manner described and illustrated achieves “a true four-point fixation of the injury and enhances both the support to the injury and reduces residual movement, thus speeding healing.” It is clear then that the strap 26 is not intended as a “tacking” or temporary holding arrangement as defined in the claims.

Moreover, as explained in Darcey (at col. 7, ll. 23-29), the “straps 26 are then placed onto the hand and wrist and the two splints 14 are positioned so that one is longitudinally aligned with the volar aspect of the hand and wrist and the other is longitudinally aligned with the dorsal aspect of the hand and wrist. The straps are then loosened or tightened if necessary to correct tightness.” Thus, the straps according to this passage in Darcey are used to fix the splints 14 to the wrist and can be *adjusted for correct tightness*. The straps 26 of Darcey are not intended to and cannot assist the physician to reposition or adjust the location of the splint on the patient’s injured limb. Darcey clearly teaches that once the straps 26 are secured with the proper tightness to the patient, they are left in place for the long term.

Therefore, the claim 40 limitation that the “laterally extending primary tacking arrangements for holding said blank in place on the injured part of the patient’s anatomy in a manner that still allows adjustment of said blank with respect to the anatomy” is not contemplated or disclosed by Darcey. Since this limitation of independent claim 40 is missing from the teachings of Darcey and Parker (which the examiner relies on to show a splint in roll form), the rejected claims are not obvious in view of the references individually or in combination. *See* M.P.E.P. 2143.03 (all claim limitations must be taught or suggested).

As explained in the pending application, the primary tacking arrangements since they are meant to be used temporarily and not for the long term, they are intentionally made of insufficient strength to rigidly immobilize the splint for the patient’s long-term use. (See paragraph [00013] of the pending application.) The present invention splint can

thus be shifted by the physician to adjust its location on the patient's anatomy. In contrast, the straps 26 once located and tightened to the wrist area of the patient as shown in Figs. 9 and 10 of Darcey do not enable the repositioning or shifting of the splint without unsecuring the straps and adjusting the position of the splint 14. The present invention primary tacking arrangements do not require this unsecuring of the tacking arrangement, and therefore provides an advantage over the Darcey splint.

Finally, it is improper to argue that the straps 26 of Darcey, which are intended for rigid, immobilizing, long-term attachment of the splint 14 to the injured wrist, can be modified to enable the "tacking" function of the claimed invention by making the straps weaker as in the present invention. Such a proposed modification is improper since it changes the principle of operation of the Darcey reference. *See* M.P.E.P. 2143.01, section IV.

For all of the foregoing reasons, applicant contends that the obviousness rejection of independent claim 40 and its dependent claims in view of Darcey and Parker individually or in combination is unsupported. The obviousness rejection should thus be withdrawn. For the same reason as claim 40, withdrawn apparatus claims 6 and 25 are likewise not obvious in view of the references individually or in combination

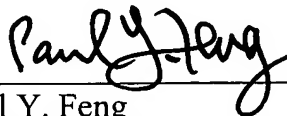
The examiner rejected claims 43, 45, and 47 under 35 U.S.C. § 103(a) over Darcey in view of Parker as applied to claim 40 above and further in view of U.S. Patent No. 6,139,513 (Grim et al.). This rejection is respectfully traversed.

According to the examiner, Grim et al. discloses a splint that uses a double-knit fabric. However, based on the examiner's reading of Grim et al., the reference adds nothing to Darcey or Parker in regard to the primary tacking arrangement that allows adjustment of said blank with respect to the anatomy as recited in independent claims 40, 6, and 25 as explained above. Since not all limitations are taught by the cited references individually or in combination, applicant respectfully submits that claims 6, 25, and 40 along with their dependent claims are patentable over this art.

In view of the foregoing, all claims are now in condition for allowance.
Reexamination and reconsideration of the application are respectfully requested and
allowance at an early date is solicited.

Respectfully submitted,

FULWIDER PATTON LLP

By: 
Paul Y. Feng
Registration No. 35,510

PYF:vmm/gbr

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201

124006.1